COMMENTS ON THE FIFTH MEETING OF THE TOBACCO WORKING GROUP
March 31 and April 1, 1969

Attachment No. 1 to these comments is a copy of the agenda for the meeting. The meeting followed the agenda as shown.

In Items No. 1 and No. 2 of the agenda Dr. Carl Baker, the Chairman, submitted to the Group attachment No. 2, consisting of a letter from the Director of the National Cancer Institute dated January 9 to the Secretary of Health, Education and Welfare regarding discussions with The Tobacco Institute, and a letter from the same person addressed to Senator Clements of The Tobacco Institute dated January 13. Dr. Baker stated that it is hoped a compromise document outlining the areas needing additional research by either NCI or program supported by the tobacco industry would be worked out in the very near future.

In his status report on the over-all program the Chairman informed the Committee that, in addition to the $200,000 previously earmarked for the Lung Cancer Task Force, the National Institutes of Health had been able to allocate approximately $800,000 for fiscal 1969 to get the program of the Tobacco Working Group underway this year. Consequently, a number of invitations to bid had been issued. These pertain to the preparation of cigarets and condensate, certain bioassay tests on these cigarets, and certain programs aimed at new and improved bioassay techniques. The Chairman was asked how much money was requested for fiscal 1970, and he informed the Group that the request had been for $1,065,000. At this point many members of the Group who are potential contractors strongly objected to the paucity of financing, and passed a resolution to the effect that, in view of the importance of this subject from a health point of view, the funds available are grossly inadequate to carry out the program.

Dr. J. A. MacMillan, from the National Heart Institute, was a new attendee to the Tobacco Working Group. Dr. Guerin, of the Oak Ridge Laboratories, has also been proposed as a member. Dr. MacMillan stated that the National Heart Institute carries on very little research on smoking, and that most of their effort is in the epidemiological field. He stated they have very few grants in which smoking dominates the experimental design. Dr. Saffiotti suggested the addition of Dr. Jerome Kleinerman, pathologist from St. Luke's Hospital at Northwestern University, as a member of the Committee.

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With regard to item No. 3, "Selection of cigarets for bioassays and chemical assays for entering the system of evaluation," the subject of the Reference Cigaret came up several times during the meeting, and was finally taken up seriously under item No. 6. It was in general agreed to use the Reference Cigaret prepared by the University of Kentucky as an example of a cigaret containing high tar (FTC tar equals 36 mg) and high nicotine (2.2 mg/cigt). In the course of the discussion it was pointed out by Dr. Wynder and others that apparently there has been a change in tobacco blend, such that cigarets which yield lower tar and nicotine also have lower carcinogenic potency on a per gram of tar basis. It was proposed in the Group that this hypothesis be attested in the checkout of the bioassay system. Consequently, the cigarets to be selected would include the Reference Cigaret and one or two other unfiltered cigarets in which low tar and nicotine are achieved by (a) selection of tobaccos in the blend and (b) by the addition of stem material to the extent of 20 or 25%. No direct action of the Committee was taken in this regard, but it is assumed that details will be worked out between Dr. Umberto Saffiotti, the Program Director, and Subgroup 1, which is responsible for designing cigaret prototypes.

In the course of this discussion Dr. Baker emphasized the need for standardizing tests, if we are to compare product prototypes. He said he is willing to back away from his earlier argument for testing brands. He stated that we should not select samples for the convenience of investigators, but samples which are expected to produce "low tumors." As a result, he urged the various subgroups to tighten up their protocols, and referred particularly to Subgroup 3, from which he requested more specific protocols for chemical assay.

At this point Dr. Saffiotti passed out attachment No. 3 which is a list of projects awarded in contracts in fiscal year 1969. Of particular interest are the two new bioassay tests which are of special interest to Dr. Saffiotti. Project No. 3 involves intragastric intubation of cigaret smoke condensates into experimental animals. Upon questioning Dr. Saffiotti regarding this technique, he stated it was an attempt to determine whether or not tobacco condensate has systemic effects "because tobacco tars are being swallowed by the smoker." The second technique of special interest is found in Project No. 6 in which it is proposed tobacco condensate be introduced by intratracheal installation technique in Syrian hamsters. Upon direct questioning, Dr. Saffiotti stated that this had already been tried, without observing any carcinogenesis, but that further experiments are warranted, since the technique had been found useful in the evaluation of pure compounds.

The remainder of the meeting was largely given over to a discussion of interface issues between various pairs of subgroups. These resulted in the preparation of a statement from Subgroup 3 regarding the analysis of cigaret smoke and smoke condensate, which is shown herein as attachment No. 4.

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It was recommended to the NCI staff that they acquire some staff assistance to flesh out this outline for the preparation of a smoke analysis protocol. It was also recommended that the contractor dealing with this subject should have some sophistication in methods development, so that some of the unresolved problems could be studied.

On the afternoon of Tuesday, April 1, the Tobacco Working Group as a whole met again to discuss various problems. In the course of these discussions, the following points were made: the Bioassay Subgroup 2 recommends that bioassay tests be done in two laboratories as a means of checking on the bioassay results. They recommended that dose response data be obtained, and that chemical tests be determined on each monthly batch of condensate as a routine quality control of the batches. More detailed chemical analyses should be made of various sample types to distinguish between the condensates of various cigarets.

Dr. Wynder pointed out that with STS mice he is observing tumor promotion in 8-9 weeks with 30% papillomas in 12 weeks by painting three times a week. He suggests that possibly STS mice may be useful in a 16-week study for quick results. Dr. Wynder is publishing a paper to the effect that the tar from 100% stem cigaret has low tumor-promoting capacity.

It is evident that NCI has taken control of this program. At one time it was contemplated that the direction of the program would be under Dr. Paul Kotin; however, Dr. Kotin has "resigned" from the Group, and his assistant, Dr. Hans Falk, has failed to show at the last two meetings. In the meantime, Dr. Umberto Saffiotti has been appointed Program Director. He now carries the title of Assistant Director of NCI. It is quite evident from these changes that the National Institute for Environmental Health at the Research Triangle is being frozen out of the tobacco and health program by the NCI.

The next meeting of the TWG is tentatively scheduled for September 3 and 4. At that time it is proposed to have a number of outside speakers for the purpose of having a seminar on various subjects relating to smoking and health. Proposed speakers are Dr. Green, Dr. Huebner, and Dr. Auerbach. Subjects of interest were stated to be (1) consideration of known cancer problems; (2) in vitro tests for quick bioassay; (3) fractionation of tobacco smoke condensate and evaluation to indicate active chemicals; and (4) cigaret designs for future bioassay tests.

Dr. Senkus submitted attachment No. 5 showing historical data on tar and nicotine for American cigarets. Dr. Tso submitted attachment No. 6 on "Anticarcinogenic Substances in Tobacco Smoke."

cc: Mr. R. N. Saleeby, Mr. Alex Holtzman, Dr. T. S. Osdene, Dr. R. Fagan, Mr. R. D. Carpenter

April 7, 1969

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